

## REMARKS

The Official Action of December 4, 2009, has been carefully reviewed, and in view of the above amendments and the following remarks, reconsideration and allowance of the pending claims are respectfully requested.

At the outset, the undersigned counsel for Applicants would like to express her gratitude to Examiner Flick for the courtesies extended during the telephonic interview conducted on March 1, 2010. During the interview proposed amendments to claim 1 were discussed and counsel explained the importance of the relative relationship of the electrode to the bevel of the injection needle. Although no agreement was reached, Applicants appreciate the Examiner's willingness to further discuss possible amendments, if needed, to obtain allowance.

In the above Official Action claims 1-7 and 9-17 were rejected on the ground of obviousness-type double patenting. In response thereto, a Terminal Disclaimer and the requisite fee are being submitted herewith.

In addition, claims 1-11 stand rejected as being obvious over Eggers et al. (U.S. Patent No. 6,106,524) in view of Shapland et al. (PCT Publication No. WO 99/04851), and claims 12-17 stand rejected as being obvious over Haim et al. (U.S. Patent No. 6,309,370) in view of Eggers et al. and Shapland et al. For at least the following reasons, Applicants respectfully traverse these rejections.

As set forth above, independent claims 1, 12 and 15 have been amended to recite, *inter alia*, an "electrode, separate and distinct from said injection needle, fixed at said distal end portion of said insertion member and spaced a predetermined distance from a bevel of said injection needle."

A description of the separate and distinct electrode being fixed to the insertion member is provided in Paragraph [0068] of the present specification. Further, Paragraph [0069] describes the importance of having the electrode spaced from the bevel of the injection needle. As set forth therein, a large change in the cardiac action potential is realized when the electrode is in contact with blood versus when the electrode is in contact with cardiac tissue. However, this is not the case when the electrode is in contact with just the surface of the cardiac tissue versus when the electrode is inside the cardiac tissue. As such, in order to ensure that the injection needle is properly located within the cardiac tissue when the large change in cardiac action potential is recognized (i.e., such as when the electrode just reaches the surface of the cardiac tissue), the bevel of the injection needle is spaced a predetermined distance distal from the electrode.

As recognized by the Examiner, "Eggers does not specifically disclose that an electrode is fixed at the distal end portion of the insertion member." (Official Action, page 4, last line - page 5, line 1). With the Eggers arrangement, it is impossible to detect whether or not the leading edge of the biopsy needle 130 securely punctures the target tissue as there is no predetermined spacing between the electrode and the needle 130.

The Examiner thus relies upon Shapland to supply the teaching found to be lacking in the primary reference to Eggers. However, in Shapland, the needle 148 is formed with an electrically conductive material and functions as a delivery electrode (Page 7, lines 23-24), that is, "the needle 148 functions as a first electrode 160" (Page 8, lines 5-6). Thus, Shapland fails to suggest an electrode "separate and distinct from said injection needle," as recited in amended claim 1. Further, since the

needle functions as the electrode in Shapland, it is not possible for the electrode to be "spaced a predetermined distance from ... said injection needle," as also recited in amended claim 1.

In contrast, the claimed invention has an electrode, ***separate and distinct*** from said injection needle, fixed at said distal end portion of said insertion member and spaced a predetermined distance from a bevel of said injection needle.

In rejecting claims 12-17, the Examiner relies upon Haim et al. as the primary reference, in combination with Eggers and Shapland. In contrast to independent Claims 12 and 15, the electrodes in Haim et al. are disposed on the distal end of the sheath 26. Even combining the teaching of Haim et al. and Eggers et al., and as recognized by the Examiner, the prior art does not "specifically disclose that an electrode is fixed at the distal end portion of the insertion member" (Office Action Page 8, lines 2-3), and hence the Examiner also relies upon Shapland. However, as discussed above, the needle 148 in Shapland "functions as a first electrode 160". Thus, Shapland fails to suggest an electrode "separate and distinct from said injection needle," as recited in amended claims 12 and 15. Further, since the needle functions as the electrode in Shapland, it is not possible for the electrode to be "spaced a predetermined distance from ... said injection needle," as also recited in amended claims 12 and 15.

For at least the reasons set forth above, Applicants submit that the prior art relied upon by the Examiner does not disclose or suggest an electrode separate and distinct from said injection needle fixed at the distal end portion of the insertion member and spaced a predetermined distance from the bevel of the injection needle

disposed at the distal end portion of said insertion member for measuring a cardiac action potential.

The dependent claims are allowable at least by virtue of their dependence from allowable independent claims. Thus, a detailed discussion of the additional distinguishing aspects recited in the dependent claims is not set forth at this time.

### **CONCLUSION**

In view of the above amendments and remarks, Applicants respectfully submit that the claims of the present application are now in condition for allowance, and an early indication of the same is earnestly solicited.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference would be helpful in resolving any remaining issues pertaining to this application; the Examiner is kindly invited to call the undersigned counsel for Applicant regarding the same.

Respectfully submitted,

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